

NCT04187989

Official Title: Social Media Intervention for Cannabis Use in Emerging Adults

Date of IRB Approval: 8/22/2019

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Project Verdi

Company or agency sponsoring the study: National Institute of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Erin E. Bonar , PhD, University of Michigan Department of Psychiatry

Study Coordinator: Lyndsay Chapman, MPH, University of Michigan Department of Psychiatry

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to e-sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether sharing information on social media affects behavior and other aspects of young peoples' lives. This research will be a randomized pilot test of two social media interventions (secret Facebook groups) for increasing well-being. You will be asked to complete a baseline survey and then join a secret Facebook group where e-coaches will share information for 8 weeks. We will ask you to complete another survey at 3 months and again at 6 months. You will be asked to share a selfie to confirm your identity and pictures of urine drug screens that will be sent to you and that you will self-administer at each. Information about things such as your stress, substance use

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Page 2 of 14

Consent Subtitle: _____

Consent Version: _____

and mood will be collected for this research study. You can earn up to \$110 in e-gift cards and your participation in the study will last 6 months.

This study involves a process called randomization. This means that the intervention you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include loss of confidentiality or feelings of discomfort as a result of being asked personal questions. More detailed information will be provided later in this document.

This study may not offer any benefit to you now, but may benefit others in the future from the knowledge gained from this study. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 6 months. Your participation in the study will be over after you complete a 6-month follow-up survey and urine screening.

Participation in the study is voluntary.

If you choose to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

We're doing a study to learn more about how social media can be used to share health and wellness information with young people and how social media affects behavior and other aspects of young peoples' lives. The purpose of the study is to develop and test social media interventions to help young people increase well-being and reduce risky behaviors. The study will help us learn about ways to deliver wellness information in a way that is appealing and helpful to young people who use Facebook.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Participants who take part in this study are 18 to 25 years of age and qualified for the study by completing a short eligibility survey.

3.2 How many people are expected to take part in this study?

Approximately 160 total subjects are expected to participate in this research study. 80 subjects will be assigned to Group 1 and 80 subjects will be assigned to Group 2.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to join the study, we will ask you to complete a 45-60 minute baseline survey. The survey will ask questions about your social media use, interactions with your friends, and health behaviors including alcohol and drug use, and injury. After completing the survey, you will be asked to submit a 'selfie' where you hold up a homemade sign with the current date and time. The study staff will use your selfie to be sure you are who you say you are by checking your selfie picture against your Facebook profile pictures. If you don't submit a selfie or if study staff can't confirm your identity, you won't be able to continue in the study. The study staff will send you a urine drug screen via priority mail and you will be asked to send a picture of your results. After you send us the picture you will dispose of the urine drug screen test yourself. You must also agree to follow the rules of the Facebook Group User Safety Agreement (below).

Once we confirm your identity, you will be randomly assigned (like flipping a coin) to one of the study groups and asked to join the secret Facebook page for that group for 8 weeks. You will also receive a friend request from an e-coach. The groups will be divided by age (18-20 year olds, and 21-25 year olds) and residence in states with/without legal recreational cannabis. The groups are:

Group 1: You will have access to the secret Facebook page that will deliver health information focused on increasing well-being and reducing risky behaviors. This information will be posted by e-coaches. You can interact with the e-coaches as well as other study members in your group.

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Group 2: You will have access to the secret Facebook page that will share news and other information about things like entertainment, sports, weather and current events.

We'll send you weekly reminders to check out the secret Facebook group page during the 8 weeks. You will be asked to complete 2 surveys during the several months. These surveys will be done at 3-months and 6-months from the time that you first joined the study. Surveys will ask the same kinds of questions as today's survey and will take about 45 minutes to complete. When it's time for your follow-up surveys, you'll receive an email or text invitation with a link and password to access the surveys. The study staff will mail you a urine drug screening at the same time as you take each follow up survey and you will be asked to send a picture of your results.

4.2 How much of my time will be needed to take part in this study?

Today's baseline survey will take 45-60 minutes to complete. The amount of time you spend during the 8-week secret Facebook group is up to you. The 3 and 6 month surveys will each take about 45-60 minutes of your time.

4.3 When will my participation in the study be over?

You will be involved with the study in total for approximately 6 months. Your participation in the study will be over after you have completed the 6 month follow up survey.

4.4 What will happen with my information and/or biospecimens used in this study?

Biospecimens will not be collected, stored, or shared outside of the study. Once the urine drug screens are completed you will be asked to dispose of them yourself.

Your collected information and biospecimen results may be shared with the sponsor of this study (National Institutes of Health). Your collected information may also be shared with other researchers, here, around the world, and with companies but only if you sign a new consent for that research.

The information we collect from you may be stripped of identifiers (meaning any information that would identify you, like name or email, would be removed) and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

*****FACEBOOK GROUP USER SAFETY AGREEMENT*****

We want to keep each other safe, so by agreeing to join the study you will be agreeing to the following safety rules. If you begin the study and then later choose not to follow these rules, your ability to interact within the group page may be removed.

Get Involved You'll likely get the most out of this experience through interaction, liking posts and comments, posting to the page, and commenting on other group members' posts.

Keeping Your Info Undercover The secret Facebook pages will not contain any of your survey responses or contact information. All interaction and content (i.e. likes, posts, comments) in the group will be



viewable to other participants in the group, but will be secret to others outside the group; meaning all of your other 'Friends' on Facebook will not be able to view the group, or search for it, or know that you are a member of it (i.e. it will not appear on your list of 'Groups' on your profile).

Shut it Down Please close your Facebook webpage if you walk away from your device; leaving it open and viewable could show the private content of the group to others.

Keeping it Real (and Relevant) Posts and comments should be relevant to or related to questions or statements about the topics/discussions which have been presented.

Keep It On The Down Low If you see someone from the group somewhere else online or have met in real life, you may not discuss their membership in this group with, or in front of, other people (in person or online). Please respect the other person's right to privacy.

Making Friends You can "friend" other members of the group on your personal Facebook pages; you are also allowed to decline or ignore friend requests from other group members.

Don't Yuck Someone Else's Yum Be respectful of others' opinions and respect that we are all different. Derogatory and degrading interactions, name calling, insults, and trolling will not be tolerated.

Just Don't Go There Posting comments regarding the following are **prohibited**: 1) asking for or telling others where to find drugs/alcohol; 2) advertisements for a business; 3) graphic or disturbing photos, videos or other media. If you're not sure about something that you want to post, email us at projectverdi@med.umich.edu.

Two Strikes and You're Out. If any of these terms are violated, the e-coach will privately contact anyone involved. The first violation will result in a warning and a reminder of this agreement. A second violation will result in a restriction of your ability to participate in the group and you will no longer be able to earn points.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are loss of confidentiality and feelings of discomfort as a result of being asked personal questions.

Some of the questions that will be asked are about sensitive or personal information such as your alcohol or drug use. These questions may make you feel uncomfortable or anxious. You may skip any question you don't want to answer and you are free to leave the study at any time.

As with any research study, there may be additional risks that are unknown or unexpected. It is important that you know we will not share your survey answers with any authorities, however no guarantees can be made regarding third-party access to data sent via internet or phone.

See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any problems that you have during this study. You should also tell your regular doctors.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. Some people may find that answering the survey questions is helpful. In the secret Facebook group page, you may learn more about cannabis use and other health behaviors. The study website and Facebook group pages will contain information on national resources including crisis hotlines and resources for substance use and mental health treatment. We hope this study will help us understand ways to deliver appealing and helpful interventions through social media.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Participation in this study is voluntary. If you choose not to participate, access to your Facebook account will not be affected in any way.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

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You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

It is not anticipated that any harm would be experienced if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will get an e-gift card after completing each study activity listed below. You must finish each survey to receive your gift card, but you can still skip any question you don't want to answer.

Study Activity	Gift Card Amount
Baseline survey, selfie verification, urine drug screening, and join secret Facebook group	\$35
3-month survey	\$35
6-month survey	\$40
	Total: \$110

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

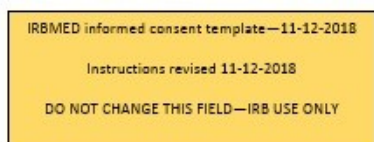
9.1 How will the researchers protect my privacy?

You may be worried about the privacy of your answers. The researchers will try to minimize loss of confidentiality in the following ways. Every effort will be made to protect your identity. We won't share your answers with anyone except the researchers of this study, but if we learn about child abuse, or that you are at risk of harm to yourself (suicide) or others (homicide), we may have to notify the authorities or parents of minors. We will ask for contact information so that we can contact you about the study and to send your electronic gift cards. This personal information will not be connected to any of your survey answers. Your surveys will be coded with a number and stored in a file that is separate from your name, email address, or any other contact information. Computer data files will be kept on secure servers at the University of Michigan and saved with password protection. Any reports or articles that we write will not contain any information that could allow somebody to identify you.

Secret Facebook group pages will be viewable by staff and other study members in that group. This means that others in the group may see your profile name and profile information depending on your personal privacy settings. All study members must agree to follow the rules of the User Safety Agreement to help protect everyone's privacy. Although all participants must agree to follow these rules and violations will be taken seriously, it is possible that another participant in the secret group may not adhere to the rules and share your private information with others outside the group. Your activity on Facebook is still accessible to Facebook and subject to the app's terms of use. We encourage you to use a strong password/code on your phone (mix of lower case and upper case letters, numbers, and symbols) and to view the study group in private spaces. We have also obtained a Certificate of Confidentiality which helps make sure that all your identifying information remains confidential.

Your 'selfie' will not be connected to any of your information. We will destroy your selfie when your Facebook group ends at 8 weeks. Your photos of your urine drug screens will not be connected to any of your information that could allow somebody to identify you.

Here is additional information about Facebook and Privacy information:



- We will provide you with instructions on how to locate your privacy settings in the event that Facebook changes their privacy settings.
- The Facebook group pages will be secret and confidential, meaning only members of the secret group can view the group; all of your other friends on Facebook will not be able to view the group, or search for it, or know that you are a member of it (i.e. it will not appear on your list of 'Groups' on your profile).
- The researchers will not download information from any individuals' Facebook pages or profiles.
- We encourage you to close out of the Facebook webpage when you are not using it; although you will not be able to add other people to the secret Facebook group page, leaving the webpage or device open could unintentionally show the content to others.
- Information on Facebook Privacy Policies can be found at:
<https://www.facebook.com/about/privacy>

The online surveys are designed and administered using Qualtrics Research Suite (<http://www.qualtrics.com/>) through the University of Michigan. Qualtrics is dedicated to protect all customer data using industry best standards. There are security precautions in place to protect against unauthorized access, but there is still a small risk of unauthorized access. There are systems in place that prevent the survey from being taken more than once. No identifying information is directly linked to your answers. For more information, Qualtrics security and privacy statements can be found at <http://www.qualtrics.com/security-statement> and <http://www.qualtrics.com/privacy-statement>.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
 - Make sure the study is done safely and properly
 - Learn more about side effects
 - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article or presented at a scientific meeting, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information

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- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my information expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Erin E. Bonar, PhD
Mailing Address:	North Campus Research Complex, Building 16 2800 Plymouth Road Ann Arbor MI 48109-2800
Telephone:	734-764-7936
Study Coordinator:	Lyndsay Chapman
Mailing Address:	North Campus Research Complex, Building 16 2800 Plymouth Road Ann Arbor, MI 48109-2800
Telephone:	734-489-9535
Email:	lych@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768

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Instructions revised 11-12-2018

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Fax: 734-763-1234

e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. *(Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

[Please click here to save or print a copy of this consent form.](#)

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information on this form. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

If you agree to participate in this study, please click “yes” to the question below to enroll in the study and enter the baseline survey.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____



submit
button